

REMARKS

In response to the Office Action dated October 4, 2005, Applicants respectfully request reconsideration based on the above claim amendments and the following remarks.

Submitted herewith is a Declaration under 37 CFR §1.131.

Status of Claims

Claims 1-25 have been rejected by the Examiner. Claims 26-28 have been newly added, leaving Claims 1-28 for consideration upon entry of the present amendment. Applicants also provide remarks herein that remove a cited reference as prior art, thereby obviating related rejections.

§105 Requirement for Information

Regarding paragraph 3 of the office action.

In paragraph 3 of the office action, the Examiner has stated that the Applicants must provide copies of each publication which any of the Applicants authored or co-authored which describe the disclosed subject matters of CT calibration using phantoms and mass scoring.

Inquiry was made of the three co-inventor Applicants. To the best of their recollections, none of the three co-inventor Applicants have authored or co-authored any publications which describe the disclosed subject matters of CT calibration using phantoms and mass scoring. Applicants submit that they have met the Examiner's requirement as stated in paragraph 3 of the office action.

Regarding paragraph 4 of the office action.

In paragraph 4 of the office action, the Examiner has stated that the Applicants must provide the title, citation and copy of each publication that is a source used for a description of the prior art in the disclosure. For each publication, the Examiner has requested a concise explanation of that publication's contribution to the description of the prior art.

Inquiry was made of the three co-inventor Applicants. Because of the length of time that has passed since filing the patent application (it was filed on 7/26/02), the Applicants did not recall any specific articles in the CT calibration area. However, the Applicants did identify the names of several key individuals (Agatston/Janowitz, Shemesh, Woodhouse, and Carr) that to the best of their knowledge were publishing articles and working in the CT calibration area around the time of the filing of their patent application. A search was performed on the Internet in the indices of several medical journals to locate articles written by these individuals between 1995 and 2002. These articles were reviewed by one of the Applicants, Kishore Acharya, to determine which (if any) of them appeared to be relevant to the prior art description. The selected articles, along with Kishore Archarya's recollection of the authors' contributions to the description of the prior art are listed below and are not necessarily considered relevant to patentability by Applicants for §105 purposes. A copy of each article referenced below is included herein.

Author: Agatston and Janowitz

The Agatston/Janowitz (AJ) scale was the standard for determining the amount of calcium present in the cardiac system in a patient. Thus, the inventors believe that Agatston and Janowitz's contribution to the description of the prior art is their AJ scale representing the amount of calcium present in the cardiac system of a patient. An article authored by Agatston and Janowitz believed to be a source used for a description of the prior art in the disclosure is listed below.

“Quantification of Coronary Artery Calcium Using Ultrafast Computed Tomography”, by Agatston and Janwoitz et al., JACC Vol. 15 No. 4, March 15, 1990, 827-832.

Author: Shemesh

Shemesh performed studies and wrote articles related to the connection between calcium in a cardiac artery and the risk of a cardiac event (or heart attack). Thus, the inventors believe that Shemesh's contribution to the description of the prior art is in the connection between calcium in a cardiac artery and the risk of a cardiac event. Articles authored by Shemesh believed to be sources used for a description of the prior art in the disclosure are listed below.

“Calcification of Coronary Arteries: Detection and Quantification with Double-Helix CT”, by Joseph Shemesh, MD, and Sara Apter, MD, et al, Cardiac Radiology, December 1995, Volume 197, Number 3, 779-783.

“Characteristics of Coronary Calcification in Patients with Acute vs. Chronic Coronary Events, Quantified by Multi-Detector Spiral Computerized Tomography”, by J. Shemesh, MD and M. Motro, MD, 1130, 11:15AM, 502.

“Double-Helical CT as a New Tool for Tracking of Allograft Atherosclerosis in Heart Transplant Recipients”, by Shemesh, M.D. and Tenenbaum, MD, PhD, et al, Investigative Technology, Vol. 34, Number 7, July 1999, 485-488.

“Coronary Calcium Measurements by Double Helical Computed Tomography: Using the Average Instead of Peak Density Algorithm Improves Reproducibility”, by Shemesh, M.D. and Tenenbaum, MD, PhD, et al, Investigative Radiology, Vol. 32, Number 9, September 1997, 503-506.

“Tracking Coronary Calcification by Using Dual-Section Spiral CT: A 3-Year Follow-up”, by Shemesh, MD and Apter, MD, et al, Radiology, Volume 217, Number 2, November 2000, 461-465.

Author: Woodhouse

Woodhouse performed studies and wrote articles related to using a registration mark to line up the images to perform calcium scoring. Thus, the inventors believe that Woodhouse's contribution to the description of the prior art is in the use of a registration mark to line up the images to perform calcium scoring. Articles authored by Woodhouse believed to be sources used for a description of the prior art in the disclosure are listed below.

“Coronary Arteries: Retrospective Cardiac Gating Technique to Reduce Cardiac Motion Artifact at Spiral CT”, Woodhouse et al., Radiology 1997, Vol 204: 566-569.

“Measuring the Performance of EKG-Based Image Selection for the Purpose of Cardiac Calcification Scoring”, Mitsa, et al, Proceedings of The First Joint BMES/EMBS Conference Serving Humanity, Advancing Technology, Oct. 13-16, 1999, Atlanta, GA, USA.

Author: Carr

Carr performed studies and wrote articles related to the correlation between a particular calcium score and the probability of a cardiac event (or heart attack). Thus, the inventors believe that Carr’s contribution to the description of the prior art is in the correlation of a particular calcium score to the probability of a cardiac event. Articles authored by Carr believed to be sources used for a description of the prior art are listed below.

“Evaluation of Subsecond Gated Helical CT for Quantification of Coronary Artery Calcium and Comparison with Electron Beam CT”, by Carr, et al, American Journal of Roentgenology, 2000; 174:915-921.

“Coronary Artery Calcium Scores Correlate Strongly Between Fast Gated Helical and Electron Beam Computed Tomography”, by Carr, et al, Abstracts of the 39th Annual Conference on Cardiovascular Disease Epidemiology and Prevention, 1106:13.

“Coronary Artery Calcium Quantification with Retrospectively Gated Helical CT: Protocols and Techniques”, Carr, et al, The International Journal of Cardiovascular Imaging, 2001, 17:213-220.

“Calcium Score with Electron Beam and Single Slice Helical CT: A Three Center Study”, by Acharya, PhD, et al, 142, 10:54 AM, 2000

“Coronary Calcium: The Case for Helical Computed Tomography”, by J. Jeffrey Carr, M.D., M.S., Journal of Thoracic Imaging, 16.

“Measuring the Performance of EKG-Based Image Selection for the Purpose of Cardiac Calcification Scoring”, by Mitsa, et al, Proceedings of The First Joint BMES/EMBS Conference Serving Humanity, Advancing Technology, Oct. 13-16, 1999, Atlanta, GA, USA.

Applicants submit that they have met the Examiner's requirement as stated in paragraph 4 of the office action.

Regarding paragraph 5 of the office action.

In paragraph 5 of the office action, the Examiner has stated that the Applicants must provide the title, citation and copy of each publication that any of the Applicants relied upon to develop the disclosed subject matter that describes Applicants' invention, particularly as to developing CT calibration using phantoms and mass scoring.

Inquiry was made of the three co-inventor Applicants. To the best of their memory and after a review of their files, none of the Applicants know of any publication(s) that they relied upon to develop the disclosed subject matter that describes Applicant's invention.

Applicants submit that they have met the Examiner's requirement as stated in paragraph 5 of the office action.

Regarding paragraph 6 of the office action.

In paragraph 6 of the office action, the Examiner has stated that the Applicants must provide the title, citation and copy of each publication that any of the Applicants relied upon to draft the claimed subject matter.

Inquiry was made of the three co-inventor Applicants. To the best of their memory and after a review of their files, none of the Applicants know of any publication(s) that they relied upon to draft the claimed subject matter.

Applicants submit that they have met the Examiner's requirement as stated in paragraph 6 of the office action.

Regarding paragraph 7 of the office action.

In paragraph 7 of the office action, the Examiner has asked the Applicants to state whether any search of prior art was performed.

Inquiry was made of the three co-inventor Applicants. To the best of their memory and after a review of their files, Applicants state that no prior art search was performed.

Applicants submit that they have met the Examiner's requirement as stated in paragraph 7 of the office action.

Regarding paragraph 8 of the office action.

In paragraph 8 of the office action, the Examiner has asked the Applicants to state the specific improvements of the subject matter of Claims 1-25 over the disclosed prior art and indicate the specific elements in the claimed subject matter that provide those improvements.

With regard to Claim 1, at the present time, Applicants believe that the specific improvements over the disclosed prior art include the ability to utilize a calibration curve equation to convert patient pixel values into patient density values in order to improve the reproducibility of the amount of calcium present in a patient cardiac system. The specific elements in Claim 1 that provide these improvements include: obtaining patient image data; identifying calcium plaque in said patient image data, wherein said calcium plaque is associated with a plurality of discrete patient pixel elements and wherein each of said patient pixel elements includes a patient pixel value expressed in Hounsfield units; converting said patient pixel values into patient density values using a calibration curve equation; and outputting said patient density values.”

With regard to Claim 2-15, at the present time, Applicants believe that the specific improvements over the disclosed prior art include the ability to utilize a calibration curve equation to convert patient pixel values into patient density values in order to improve the reproducibility of the amount of calcium present in a patient cardiac system. Due to their dependency on Claim 1, Claims 2-15 include at least the same elements as Claim 1 that provide these improvements.

With regard to Claim 16, at the present time, Applicants believe that the specific improvements over the disclosed prior art include the ability to utilize a calibration curve equation to convert patient pixel values into patient density values in order to improve the reproducibility of the amount of calcium present in a patient cardiac system. The specific elements in Claim 16 that provide these improvements include: creating a calibration curve equation, wherein said creating includes: obtaining phantom image data associated with a plurality of discrete phantom pixel elements corresponding to a calcium insert of known density in a phantom, wherein each of said phantom pixel elements includes a phantom pixel value expressed in Hounsfield units; graphing said phantom image data against said known density of said calcium insert; and developing said calibration curve equation for computing said patient density values in response to patient pixel values; obtaining patient image data; identifying calcium plaque in said patient image data, wherein said calcium plaque is associated with a plurality of discrete patient pixel elements and wherein each of said patient pixel elements includes a said patient pixel value expressed in Hounsfield units; converting said patient pixel values into patient density values using said calibration curve equation; and outputting said patient density values.

With regard to Claim 17, at the present time, Applicants believe that the specific improvements over the disclosed prior art include the ability to utilize a calibration curve equation to convert patient pixel values into patient density values in order to improve the reproducibility of the amount of calcium present in a patient cardiac system. The specific elements in Claim 17 that provide these improvements include: an imaging system; an object disposed so as to be communicated with said imaging system, wherein said imaging system generates image data responsive to said object; and a processing device in communication with said imaging system including software to implement the method comprising: obtaining said image data; identifying calcium plaque in said image data, wherein said calcium plaque is associated with a plurality of discrete pixel elements and wherein each of said pixel elements includes a pixel value expressed in Hounsfield units; converting said pixel values into density values using a calibration curve equation; and outputting said density values.

With regard to Claim 18-23, at the present time, Applicants believe that the specific improvements over the disclosed prior art include the ability to utilize a calibration curve

equation to convert patient pixel values into patient density values in order to improve the reproducibility of the amount of calcium present in a patient cardiac system. Due to their dependency on Claim 17, Claims 18-23 include at least the same elements as Claim 17 that provide these improvements.

With regard to Claim 24, at the present time, Applicants believe that the specific improvements over the disclosed prior art include the ability to utilize a calibration curve equation to convert patient pixel values into patient density values in order to improve the reproducibility of the amount of calcium present in a patient cardiac system. The specific elements in Claim 24 that provide these improvements include: a storage medium readable by a processing circuit and storing instructions for execution by the processing circuit for: obtaining patient image data; identifying calcium plaque in said patient image data, wherein said calcium plaque is associated with a plurality of discrete patient pixel elements and wherein each of said patient pixel elements includes a patient pixel value expressed in Hounsfield units; converting said patient pixel values into patient density values using a calibration curve equation; and outputting said patient density values.

With regard to Claim 25, at the present time, Applicants believe that the specific improvements over the disclosed prior art include the ability to utilize a calibration curve equation to convert patient pixel values into patient density values in order to improve the reproducibility of the amount of calcium present in a patient cardiac system. The specific elements in Claim 25 that provide these improvements include: a storage medium readable by a processing circuit and storing instructions for execution by the processing circuit for: creating a calibration curve equation, wherein said creating includes: obtaining phantom image data associated with a plurality of discrete phantom pixel elements corresponding to a calcium insert of known density in a phantom, wherein each of said phantom pixel elements includes a phantom pixel value expressed in Hounsfield units; graphing said phantom image data against said known density of said calcium insert; and developing said calibration curve equation for computing said patient density values in response to patient pixel values; obtaining patient image data; identifying calcium plaque in said patient image data, wherein said calcium plaque is associated with a plurality of discrete patient pixel elements and wherein each of said patient pixel elements includes a said patient pixel value expressed in Hounsfield units; converting said patient pixel

values into patient density values using said calibration curve equation; and outputting said patient density values.

Applicants submit that they have met the Examiner's requirement as stated in paragraph 8 of the office action.

Support for New Claims

No new matter has been introduced by newly added Claims 26-28. Support for newly added Claims 26-28 can be found, for example, in Claim 1 and paragraph 28 of the specification.

Rejections Under 35 U.S.C. §102(a)

Claims 1-5, 8, 9 and 15-25 stand rejected under 35 U.S.C. §102(a) as being anticipated by Hong.

Applicants traverse this rejection for the following reasons.

The subject matter of Claims 1-5, 8, 9 and 15-25 was invented prior to Hong being described in a printed publication. Submitted herewith is a Declaration under 37 CFR § 1.131 establishing conception of the invention of Claims 1-5, 8, 9 and 15-25, prior to May 1, 2002 (the printed publication date of Hong), and diligent reduction to practice of the invention prior to May 1, 2002. The Declaration and accompanying attachments show a completion of the claimed subject matter prior to the effective date of Hong (see Attachment A). Thus, Hong is not prior art.

Dependent claims inherit all of the limitations of the respective parent claim and any intervening claim.

In view of the foregoing, Applicant submits that Hong has properly been removed as a prior art reference, that Claims 1-5, 8, 9 and 15-25, and claims dependent from those claims, are in condition for allowance, and respectfully requests notice thereof.

Rejections Under 35 U.S.C. §103

Claims 6-7, stand rejected under 35 U.S.C. §103(a) as being unpatentable over Hong in view of Arnold (U.S. Patent No. 4,922,915). For at least the reasons described above with regard

to Claim 1, from which Claims 6-7 depend, Hong is not prior art. Further, Arnold does not teach or suggest all of the elements of Claims 6-7. For at least these reasons, Applicants submit that Claims 6-7 are patentable over Hong in view of Arnold.

Claims 10-14 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Hong in view of Arnold and Feldman (U.S. Patent No. 5,222,021). For at least the reasons described above with regard to Claim 1, from which Claims 10-14 depend, Hong is not prior art. Further, neither Arnold nor Feldman, alone or in combination teach or suggest all of the elements of Claims 10-14. For at least these reasons, Applicants submit that Claims 10-14 are patentable over Hong in view of Arnold and Feldman.

Conclusion

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that this application is now in condition for allowance. Accordingly, reconsideration and allowance is respectfully requested.

In the event the Examiner has any questions regarding this Amendment, Applicants' attorneys respectfully request the courtesy of a telephone conference.

In the event that there are any additional fees with respect to this Amendment, Applicants' attorneys respectfully request that such fees be withdrawn from Deposit Account No. 07-0845 maintained by Applicants' attorneys.

Respectfully submitted,

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